AGENDA
Region 9 Meeting
Albany Marriott
189 Wolf Road, Albany, NY
October 12, 2011

(Note: All times except the start time are approximate. Actual times will be determined by the amount of discussion.)

8:45 Check-in for OPTN/UNOS Kidney Paired Donation Pilot Program Meeting

9:00 OPTN/UNOS Kidney Paired Donation Pilot Program Meeting Ruthanne Hanto, RN, MPH
Program Manager, OPTN/UNOS Kidney Paired Donation Pilot Program

9:00 Registration and Continental Breakfast

10:00 Welcome/Opening Remarks David J. Conti, MD
Region 9 Councillor

- March 2011 regional meeting summary
- OPTN/UNOS committee nominations, Associate Councillor nominations
- Spring meeting date

10:15 OPTN/UNOS Update John R. Lake, MD
OPTN/UNOS President

10:50 OPTN/UNOS Committee Reports and Public Comment Proposal Discussion
Moderator: David Conti, MD

****Lunch will be served at 12:30****

Kidney Transplantation Lloyd Ratner, MD

Proposal to Clarify Requirements for Waiting Time Modification Requests (page 6-12)
Current OPTN/UNOS policies for submitting waiting time modification requests are not clear, leading to wasted time for the transplant centers that submit requests, for OPTN Contractor staff who process requests, and for the Committees that review requests. Required documentation is often missing and results in delays for transplant candidates to receive the waiting time that they may be entitled to receive under OPTN policy. With these proposed clarifications, the Committee expects to see fewer submissions of incomplete requests and faster time to implementation of approved requests.

Liver and Intestinal Organ Transplantation Lewis Teperman, MD

Proposal to Extend the "Share 15" Regional Distribution Policy to "Share 15 National" (page 13-22)
The Committee is proposing an extension of the current "Share 15 Regional" policy so that deceased donor livers (age 18 and higher) would be offered to all candidates with MELD/PELD scores of 15 or higher locally, regionally, and nationally before being offered to candidates with lower MELD/PELD scores.

Proposal for Regional Distribution of Livers for Critically Ill Candidates (Page 23-34)
This proposal would offer livers to combined local and regional candidates with MELD/PELD scores of 35 or higher ("tiered regional sharing").

Thoracic Organ Transplantation Alan Gass, MD

Plain Language Modifications to the Adult and Pediatric Heart Allocation Policies, Including the Requirement of Transplant Programs to Report in UNet℠ a Change in Criterion or Status within Twenty-Four Hours of that Change (page 35-46)

The OPTN contractor's policy evaluation plan requires that heart transplant programs record in UNet℠ changes to a heart transplant candidate's status or criterion within 24 hours, but this requirement is not written in Policies 3.7.3 (Adult Candidate Status) and 3.7.4 (Pediatric Candidate Status). The two policies state that the OPTN contractor will notify "a responsible member of the transplant team" prior to downgrading a candidate's Status, but the OPTN contractor does not notify such personnel in addition to displaying the candidate's status in UNet℠. The proposed modification includes the 24-hour requirement, removes of the notification clause, and includes edits for plain language. For consistency, the modifications also include language about potential referral of pediatric heart status exception case decisions to the Thoracic Organ Transplantation Committee.

Ad Hoc International Relations and Ethics Lisa McMurdo, RN, MPH

Proposed Revisions to and Reorganization of Policy 6.0 (Transplantation of Non-Resident Aliens), Which Include Changes to the Non-Resident Alien Transplant Audit Trigger Policy and Related Definitions (page 47-65)

This proposal clarifies the data collected about the citizenship and residency of donors and recipients. The proposal also amends the audit trigger policy, allowing the Ad Hoc International Relations Committee to review the circumstances of any transplant of non-US residents/non-US citizens and make a public report. The proposal also contains technical amendments and removal of requirements that are not enforceable.

Histocompatibility Rex Friedlander, BS, CHS

Proposed Update to the Calculated PRA (CPRA) (page 66-76)

The purpose of this proposal is to update CPRA so it can better reflect current lab practices as well the current donor pool. These revisions include updating the HLA frequencies used to calculate CPRA, the addition of the antigen C to the calculation and the removal of zero (0) as a default value.

Revision of the UNOS Bylaws, the OPTN Bylaws and the OPTN Policies that Govern HLA Laboratories (page 77-88)

This proposal revises the UNOS Bylaws and Policies that apply to histocompatibility laboratories to more closely align OPTN/UNOS requirements for member laboratories with current laboratory practices.

Living Donor Carlos Marroquin, MD

Proposal to Establish Requirements for the Informed Consent of Living Kidney Donors (page 89-105)

This proposal would establish policy requirements for the informed consent of living kidney donors. This proposal is in response to a directive from the Health Resources and Services Administration (HRSA) and based on recommendations from a Joint Societies Steering Committee composed of representatives of the American Society of Transplantation (AST); the American Society of Transplant Surgeons (ASTS); and the North American Transplant Coordinators Organization (NATCO) to the OTPN/UNOS Living Donor Committee.

Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up (page 106-122)

This proposal would require transplant programs to report required fields on the Living Donor Follow-up (LDF) form at required post-operative reporting periods (6, 12, and 24 months). The OPTN currently relies on Living Donor Follow-up (LDF) forms to collect data on the short-term health status of living donors. Data on living donors who donated in 2006 through 2009 demonstrate that many programs do not report meaningful living donor follow-up information at required reporting intervals. Consequently, to allow for meaningful analyses to objectively study the short-term effects of living donation, the transplant community must collectively improve patient information on the LDF form. The proposed minimum reporting requirements are based on recommendations from the Joint Society Work Group, which is composed of representatives from the American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), and the North American Transplant Coordinators Organization (NATCO) to the OPTN/UNOS Living Donor Committee.

Proposal to Establish Requirements for the Medical Evaluation of Living Kidney Donors (page 123-140)
This proposal would establish policy requirements for the medical evaluation of living kidney donors. This proposal is in response to a directive from the Health Resources and Services Administration (HRSA), and based on recommendations from a Joint Societies Steering Committee composed of representatives of the American Society of Transplantation (AST); the American Society of Transplant Surgeons (ASTS) and the North American Transplant Coordinators Organization (NATCO) to the Living Donor Committee.

Organ Procurement Organization Julie Mirkin, MA, RN

Proposal to Eliminate the Use of an "Alternate" Label when Transporting Organs on Mechanical Preservation Machines and to Require the OPTN Distributed Standardized Label (page 141-147)
This proposal would make labeling of these machines consistent for all deceased and living donor organs that are transported outside of donor hospitals. Current policy allows the use of an "alternate" label, or a label other than the OPTN standardized label, when transporting organs on a mechanical preservation machine. OPOs create their own alternate labels resulting in inconsistent labeling. The proposed policy changes eliminate the use of alternate shipping labels on mechanical preservation machines and require OPOs to use a new standardized label that is part of the current color-coded labeling system distributed by the OPTN contractor.

Proposal to Change the Term "Consent" to "Authorization" Throughout Policy When Used in Reference to Organ Donation (page 148-161)
The proposed modification will change the term "consent" to "authorization" throughout policy when used in reference to deceased organ donation. Currently, OPTN policy uses the term "consent" to describe the act of making an anatomical gift. However, the public associates "consent" with the medico-legal concept of "informed consent" through which physicians must give patients all the information they need to understand the risks, benefits, and costs of a particular medical treatment.

In the context of organ/tissue/eye donation after death, this blending of terms leads to misunderstandings about the act of donation that could hinder our national goal of increasing organ/tissue/eye donation and transplantation. The OPO community has responded to this circumstance by changing the donation terminology from "consent" to "authorization." This change focuses attention on the altruistic act of donation and reinforces the fact that donation after death does not involve medical treatment.

Proposal to Modify the Imminent and Eligible (I & E) Neurological Death Data Reporting Definitions (page 162-174)
The proposed policy changes clarify the definitions for determining whether a death can be classified as "imminent" or "eligible." OPOs are responsible for reporting data that classify a death as either an Imminent Neurologic Death ("imminent,") or Eligible Death ("eligible,") or neither "eligible" nor "imminent" ("neither.") The OPOs then report the "imminent" and "eligible" deaths to the OPTN. There are inconsistencies in the data reporting which have been primarily attributed to:

- OPOs interpreting the definitions in Policy 7.1 (Reporting Definitions) differently, and
- Brain death laws varying from state to state affecting the way the deaths are reported.

The Committee eliminated Multi-system organ failure as an exclusionary criteria for classifying a death as "eligible", and identified a list of organ specific exclusionary criteria that has been added to provide more detailed guidance. The Committee also made changes to the definition of "imminent" so that it is restricted to those deaths that would most likely be classified as "eligible" had brain death been legally declared. This could allow the combination of "eligible" and "imminent" deaths to mitigate the effect of the variation in brain death laws.

Policy Oversight Nancy Metzler

Proposal to Clarify and Improve Variance Policies (page 175-201)
This proposal streamlines and clarifies requirements for review and approval of variances, including gathering all requirements into one policy category for the variance application, review, approval, modification, dissolution, and

appeal processes; detailing the process for appealing a variance decision of the Committee or Board of Directors; eliminating redundancy in existing variance policies; and rewriting the variance policies using plain language.

Committee reports:

Transplant Administrators	Nancy Metzler
Pediatric Transplantation	Kishore Iyer, MD
Operations and Safety	Theresa Daly, MS, FNP
Minority Affairs	Lani Jones, PhD, MSW
Membership and Professional Standards	Mark Orloff, MD
Ethics	Richard Demme, MD
Finance	Jim Aranda, BS, MBA
CMS Update	Kimberly Valente, RN

3:00 Adjournment